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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 10/050,655   | 01/16/2002  | Damian J. Gallina    | 01-496-A                       | 7537             |
| 20306  | 7590        | 10/19/2005           |                                |                  |
| MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP<br>300 S. WACKER DRIVE<br>32ND FLOOR<br>CHICAGO, IL 60606 |             |                      |                                |                  |
|  |             |                      | EXAMINER<br>WINSTON, RANDALL O |                  |
|  |             |                      | ART UNIT<br>1655               | PAPER NUMBER     |

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/050,655 | <b>Applicant(s)</b><br>GALLINA, DAMIAN J. |  |
|                              | <b>Examiner</b><br>Randall Winston   | <b>Art Unit</b><br>1655                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33 and 39-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33 and 39-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Acknowledgement is made of the receipt and entry of the amendment filed on 07/11/2005.

Examiner acknowledges that claims 1-32 and 34-38 have been cancelled.

Claim 33 and new claims 39-58 are under examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-50 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, as the time the application was filed, had possession of the claimed invention. Claims 48 and 51 recite the limitation "for more than one day" and claims 49 and 52 recite the limitation "for more than six days" which do not appear to be disclosed within the instant specification and, thus, are deemed new matter. Applicant is required to remove the new matter from the claim or specifically point out where the phrase is found within the specification because it appears to examiner that "for more than one day" and "for more than six day" have no upper limit. The specification has only support for at most 21 days.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 39-47 and 51-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 51 recite the term "toxic concentration." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning of the above terms. There is no definition of "toxic concentration" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention. Accordingly the metes and bounds of these terms are not clearly delineated because it appears to examiner that toxic amounts could be any amount. (please note is applicant claiming "at least .01611" as the exact amount?)

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33, 40-47 and 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Guo, (*The Role of CD44 in HIV*), Dissertation Abstracts International, (1996), Vol. 57, No. 1B, p. 225 and also as evidence by Horwitz (US 6797267).

Applicant claims a pharmaceutical composition comprising HIV infected cells that have been treated with hyaluronidase and a pharmaceutically acceptable carrier or diluent.

In applicant's response on July 11, 2005, Applicant argues Guo fails to teach HIV infected that have been treated with hyaluronidase at a toxic concentration and Guo fails to teach HIV infected cells treated with hyaluronidase that form HIV immunogens or antigens that prime and activate antigen presenting cells or that exhibit reduced cell viability.

Applicant argument is not found persuasive because claims 33 and 40-47 as amended and newly added claims 54-58 are still rejected under 35 U.S.C. 102 (b) because Guo anticipates the claimed invention (see, e.g. entire article) because Guo teaches HIV infected cells that have been treated with hyaluronidase whereas Guo's same composition would also inherently have the same effect as the claimed composition when administered to a subject. (Please since applicant has not clearly defined "toxic concentrations", see 35 U.S.C. 112 2<sup>nd</sup> argument above, it appears to examiner that the newly amended claimed invention is the same as previously presented. Thus, Guo anticipates the claimed invention).

{Moreover, Please note that since Guo teaches that their utilized HIV infected cells are monocytic cells (and as evidence by Horwitz which defines (see, e.g. column 9 lines 66-67 and column 10 lines 1-4) a Peripheral Blood Mononuclear cell as and/or is a monocytic cell), Guo anticipates the claimed invention because both Guo and applicant utilize monocytic cells within their processes that are HIV infected. Also please note that it is well known in the art that the hyaluronidase enzyme within the Guo's process would have to be within some sort solution or carrier (i.e. water) when treating HIV infected monocytic cells}

Therefore, the reference is deemed to anticipate the claim invention.

**No claims are allowed.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
10-18-05  
**SUSAN COE**  
**PRIMARY EXAMINER**